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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Helene Derand

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EXAMINER

BARTON, JEFFREY THOMAS

ART UNIT

PAPER NUMBER

1753

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,827	DERAND ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Barton	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7, 8, 10-28, 30, 34, 35, 42, 43, 45 and 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7, 8, 10-28, 30, 34, 35, 42, 43, 45 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20051020</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed on 21 March 2006 does not place the application in condition for allowance.

Status of Rejections Pending Since the Office Action of 21 September 2005

2. All previous rejections are withdrawn due to Applicant's amendment.

Claim Objections

3. Claim 7 is objected to because of the following informalities:
 - a. There is no clear antecedent basis for "said at least one functional parts" in line 9 of the claim. The only similar previous recitation requires "more than one functional part".
 - b. In line 13 of the claim, "function part" is recited, although it appears "functional part" was intended.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 2-5, 7, 8, 10-13, 18-23, 28, 34, 35, 42, 43, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo in view of Zimmer et al, Karger et al, and Regnier et al.

Regarding claim 7, Amigo discloses a microfluidic device (Column 6, line 46 - Column 8, line 21) comprising a set of one or more (Column 7, lines 29-34) covered

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microchannel structures (Column 7, lines 49-55) manufactured in the surface of a planar substrate (Column 3, line 36 - Column 4, line 9); wherein the microchannel structures comprise plural functional parts (e.g. branches; Column 7, lines 37-40) that are volume-defining units (Any channel defines the volume it occupies, by its nature); wherein non-specific adsorption and hydrophilicity are optimized by a coat exposing a non-ionic hydrophilic polymer on a part of the surface of at least one of the microchannel structures (Column 4, line 53 - Column 5, line 48); Also regarding the question of optimization, generally, differences in concentration (i.e. in this case, density, thickness, or other variable of the coating) or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding claim 2, Amigo discloses the surface carrying the coat being made of organic material. (Column 3, line 36 - Column 4, line 22)

Regarding claim 3, Amigo discloses the surface of the planar substrate being made of plastic. (Column 4, lines 10-22)

Regarding claims 4 and 20, Amigo discloses the non-ionic hydrophilic polymer being attached to a polymer skeleton that is attached to the surface. (Column 4, lines 10-64)

Regarding claim 5, Amigo discloses the device comprising more than five covered microchannel structures. (Column 7, lines 29-31)

Regarding claim 8, Amigo discloses microchannel structures comprising a microcavity having a volume less than or equal to 1 μL . (Column 6, line 60 - Column 7, line 14; usual microchannel dimensions give a volume range of 0.02 - 2.5 μL)

Regarding claim 10, Amigo discloses the device being a round disk. (Column 7, lines 20-25)

Regarding claim 11, Amigo discloses the hydrophilic polymer comprising amide or ethylene oxy groups. (Column 5, lines 32-40)

Regarding claims 18 and 19, Amigo discloses the hydrophilic polymer comprising a plurality of amide groups, and being a polymerisate of monomers of acrylamide (i.e. polyacrylamide). (Column 5, lines 32-40)

Regarding claim 21, Amigo discloses covalent attachment between the hydrophilic polymer and the skeleton. (Column 4, lines 59-64)

Regarding claims 22 and 23, Amigo discloses the polymer skeleton being an organic polymer that is neutral. (Column 4, lines 32-40)

Regarding claim 28, Amigo discloses the surface of the planar substrate being made of a plastic that comprises a non-significant fluorescence for excitation wavelengths in the interval of 200-800 nm and emission wavelengths in the interval of 400-900 nm. (Column 3, line 36 - Column 4, line 9)

Regarding claim 34, Amigo discloses the plastic substrate being based on a polymer of aliphatic monomers containing polymerizable carbon-carbon double bonds. (Column 3, lines 49-54)

Regarding claim 35, Amigo discloses the monomer being ethylene or propylene. (i.e. product is polyethylene or polypropylene; Column 3, lines 49-54)

Regarding claim 36, Amigo discloses mass transport of solutes and/or particles between different functional parts of the microchannel structure using electroendoosmosis (i.e. electroosmotic flow, EOF). (Column 4, line 65 - Column 5, line 16; Column 6, lines 21-45)

Regarding claims 42 and 43, Amigo discloses inorganic materials and polymers for the channel surfaces. (Column 3, lines 8-19 and 47-49; glass is disclosed)

Regarding claim 47, Amigo discloses solute transport. (Column 4, line 65 - Column 5, line 3; EOF of the solution will lead to solute transport)

Regarding claim 54, Amigo discloses a reaction taking place within the channels of his device. (e.g. Column 12, lines 30-34 of Column 6, lines 39-41) Any such channel with microscale dimensions can be called a "reaction microcavity".

Relevant to claim 7, Amigo does not explicitly disclose the device being in a dry state that is capable of being rehydrated, nor does he disclose surfaces of device parts having a sufficient hydrophilicity for liquid to enter the part once having passed the entrance of the part. (i.e. by capillary forces) Amigo also does not explicitly disclose mass transport of solutes or particles between different functional parts of a

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microchannel structure using a liquid flow caused by non-electrokinetic forces.

Relevant to claims 12 and 13, Amigo does not explicitly disclose a device comprising a polyhydroxy hydrophilic polymer (Claim 12), or a polyhydroxy polymer selected from among polysaccharides, polyvinyl alcohols, and poly(hydroxyl alkyl vinyl ether) polymers. (Claim 13)

Zimmer et al disclose the ability of capillaries with sufficiently hydrophilic surfaces, including polymer surfaces, to draw in aqueous materials upon contact. (Pages 5-8)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Amigo by specifically providing a hydrophilic surface (such as a hydrophilic polymer surface) at a channel opening to draw aqueous fluids in by capillarity, as taught by Zimmer et al, because it would facilitate sample introduction in some applications. (e.g. biosensor)

Karger et al disclose the use of a polyvinyl alcohol coating in electrophoresis capillaries in order to minimize adsorption of analytes to the capillary walls and control electroosmosis. (Column 1, line 50 - Column 2, line 39) (Claims 12 and 13) They also disclose the subsequent drying of the coated capillaries (Column 7, lines 1-39, particularly lines 38-39), and the rehydrating of the capillaries for use in later analyses. (Column 7, line 40 - Column 8, line 43; rehydration would be inherent)

Addressing claim 7, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Amigo by providing the device in a dry state that is capable of being rehydrated, as taught by Karger et al, because it would facilitate device storage and shipping. The convenience of being able to store devices for later use, as compared to preparing the coatings immediately prior to use would have been obvious and highly desirable to one having ordinary skill in the art.

Addressing claims 12 and 13, it would have been obvious to one having ordinary skill in the art to modify the invention of Amigo by replacing his non-ionic hydrophilic coating with the polyvinyl alcohol coating taught by Karger et al, because Karger et al teach that it performs similar functions, and it would possess different reactivity that could facilitate a particular analysis. Selection of a known separation medium in capillary electrophoresis falls well within the level of ordinary skill in the art.

Regnier et al disclose bulk fluid motion caused by non-electrokinetic means.
(Column 37, lines 53-59)

It would also have been obvious to one having ordinary skill in the art to further modify the device of Amigo by using a non-electrokinetic means of moving fluid within the channels, as taught by Regnier et al, because it would prevent electrophoretic bias in the injection procedure. Additionally, if the object of the application of the hydrophilic coating was to minimize or substantially eliminate electroosmotic flow (See Amigo,

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Column 5, lines 9-16), then a non-electrokinetic means of bulk fluid motion would be required in order to have efficient fluid flow.

Also regarding claim 7 and the “adapted for mass transport of solutes and/or particles . . . caused by non-electrokinetic forces” limitation, this limitation is drawn primarily to an intended use of the device, as any fluid transport system is amenable to such means of transport. Amigo in fact discloses such non-electrokinetic fluid transport in preparing the device. (Column 9, lines 45-48) Such adaptation is considered to be present. The Regnier et al reference is primarily cited to show that such means of fluid movement in systems of this type was conventional in the art, even if this limitation were amended to more explicitly require it. In addition, Applicant’s disclosure gives absolutely no indication that a non-electrokinetic means of fluid movement is a significant part of the claimed invention. The disclosure at Page 13, lines 4-22 describes suitable means of causing fluid flow, and lists electrokinetic means (e.g. electroendoosmosis and electrophoresis) and non-electrokinetic means, with no indication that either is preferable.

Also regarding claim 7 and the “self-suction” limitation, capillary action is a conventional technique for sample introduction in techniques using tubular capillaries, and its extension to microfluidic chips involves no inventive skill. Indeed, entry of liquid by “self-suction” would inherently result from bringing a drop of aqueous liquid in contact with any inlet of a dry microfluidic system coated with a hydrophilic polymer, such as that resulting from the combination of Amigo and Karger et al.

8. Claims 14 and 24-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo, Zimmer et al, Karger et al, and Regnier et al as applied to claims 7 and 20 above, and further in view of Bergstrom et al. (US 5,250,613).

Amigo, Zimmer et al, Karger et al, and Regnier et al disclose a combined device as described in addressing claims 7 and 20 above.

None among Amigo, Zimmer et al, Karger et al, and Regnier et al explicitly disclose the use of a hydrophilic polymer that is a reaction product between ethylene oxide and a dihydroxy or a polyhydroxy compound (Claim 14), nor do they explicitly disclose the use of a polyamine skeleton (Claim 24), a polyethylene imine skeleton (Claim 25), or a skeleton with a molecular weight of 10,000 - 3,000,000 Da. (Claim 26)

Relevant to claim 14, Bergstrom et al disclose the use of a coating of an adduct of ethylene oxide and a dihydroxy or polyhydroxy compound as a hydrophilic polymer that prevents or reduces analyte adsorption to a surface. (Column 7, lines 20-24; Column 1, line 56 - Column 2, line 28)

Relevant to claims 24-26, Bergstrom et al disclose the use of a polyethylene imine skeleton with molecular weight of 10,000 - 1,000,000 Da. (Column 3, lines 15-49; Column 7, lines 41-52) Polyethylene imine is a polyamine.

Addressing claim 14, it would have been obvious to one having ordinary skill in the art to modify the invention of Amigo by replacing his non-ionic hydrophilic coating with a coating of an adduct of ethylene oxide with dihydroxy or polyhydroxy compounds, as taught by Bergstrom et al, because Bergstrom et al teach that it performs similar

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functions, and it would possess different reactivity that could facilitate a particular analysis. Selection of a known separation medium in capillary electrophoresis falls well within the level of ordinary skill in the art.

Addressing claims 24-26, it would have been obvious to one having ordinary skill in the art to further modify the invention of Amigo by replacing his non-ionic hydrophilic coating with a biopolymer (e.g. cellulose, starch) coating supported by a skeleton of polyethylene imine with a molecular weight of 10,000 - 1,000,000, as taught by Bergstrom et al, because Bergstrom et al teach that it performs similar functions, and it would possess different reactivity that could facilitate a particular analysis. Selection of a known separation medium in capillary electrophoresis falls well within the level of ordinary skill in the art.

9. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo, Zimmer et al, Karger et al, and Regnier et al as applied to claim 11 above, and further in view of Malmsten et al.

Amigo, Zimmer et al, Karger et al, and Regnier et al disclose a combined device as described in addressing claim 11 above.

None among Amigo, Zimmer et al, Karger et al, and Regnier et al explicitly disclose the use of a polymer comprising one or more blocks of polyoxyethylene chains (Claim 15), the use of polyethylene glycol as the hydrophilic polymer (Claim 16), or the use of polyethylene glycol with a methoxy group at the end that does not bind to the surface as the hydrophilic polymer. (Claim 17)

Malmsten et al disclose the use of polyethylene glycol as a hydrophilic coating for minimizing protein adsorption in biological applications. (Abstract, Introduction) A variety of polyethylene glycol was disclosed that had methoxy end groups that do not bind the surface (Tables 2 and 3, Pages 512-515)

It would have been obvious to one having ordinary skill in the art to further modify the invention of Amigo by replacing his non-ionic hydrophilic coating with the polyethylene glycol coating taught by Malmsten et al, because Malmsten et al teach that it performs similar functions, and it would possess different reactivity that could facilitate a particular analysis. Selection of a known separation medium in capillary electrophoresis falls well within the level of ordinary skill in the art.

10. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo, Zimmer et al, Karger et al, and Regnier et al.

Amigo, Zimmer et al, Karger et al, and Regnier et al disclose a combined device as described in addressing claim 7 above. Amigo also suggests performing affinity assays in his system. (Column 10, lines 28-47)

Regnier et al also disclose a method of performing an analytical assay (Example 2) comprising preparing a sample (Column 42, lines 63-65); running an assay reaction (Column 42, line 65 - Column 43, line 7), and detecting the result of the assay reaction, wherein the result is a measure of the activity of the sample. (Column 43, lines 12-20) Regnier also states that "the method of the invention can be carried out in any conventional capillary electrophoresis system." (Column 42, lines 8-10)

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It would have been obvious to one having ordinary skill in the art to use the device disclosed by Amigo, Zimmer et al, Karger et al, and Regnier et al in an assay procedure such as that disclosed by Regnier et al, because Regnier et al suggest performing it in any conventional system, including microfluidic devices (Column 42, lines 8-12), and Amigo suggests preparing a device with affinity agent in the coating (Column 10, lines 28-47), providing strong suggestion of its suitability for use in such assays. It appears to the examiner that any conventional assay procedure making use of the device of Amigo (with affinity agents) would read on the claim, as the sample preparation and running steps would be inherent in any procedure, and the detected result of any assay would provide a measure of sample activity.

11. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo, Zimmer et al, Karger et al, and Regnier et al as applied to claim 35 above, and further in view of Daecher et al.

Amigo, Zimmer et al, Karger et al, and Regnier et al disclose a combined device as described above in addressing claim 35. Amigo also discloses the suitability of a broad range of polymers for forming the substrate of his device, suggesting the use of other suitable materials ("and the like" - Column 3, lines 36-60)

None among Amigo, Zimmer et al, Karger et al, and Regnier et al explicitly disclose using a norbornene as a monomer.

Daecher et al disclose the preparation of polymer sheets suitable for forming microfluidic systems (Column 9, lines 55-65) using polymers made using norbornene monomers. (Column 14, lines 9-32)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Amigo by forming it using a polymer sheet made using norbornene monomers, as taught by Daecher et al, because Amigo suggested the use of other suitable polymers, and Daecher et al teach the suitability of these materials for forming microfluidic devices.

12. Claims 7 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karger et al in view of Zimmer et al, Van Alstine et al, and Regnier et al.

Relevant to claim 7, Karger et al disclose a microfluidic device (Column 2, lines 27-32) comprising covered microchannel structures (Column 9, line 18 - Column 10, line 4) manufactured in the surface of a planar substrate (Column 2, lines 27-32), wherein non-specific adsorption and hydrophilicity are altered by a coat exposing a non-ionic hydrophilic polymer on a part of the surface of at least one of the microchannel structures. (Column 2, lines 20-39) They also disclose the subsequent drying of the coated capillaries (Column 7, lines 1-39, particularly lines 38-39), and the rehydrating of the capillaries for use in later analyses. (Column 7, line 40 - Column 8, line 43; rehydration would be inherent)

Relevant to claim 27, Karger et al disclose the substrate being made of plastic (Column 6, lines 15-22), and preparation of a bare capillary surface (silica) with acid to ensure proper surface functionalization for the coating reaction. (Column 7, lines 1-11)

Karger et al do not explicitly disclose plural functional parts, at least one of which is coated with hydrophilic polymer into which aqueous liquid can enter by self-suction when the liquid has passed the entrance of the functional part, or mass transport of solutes or particles between different functional parts of a microchannel structure using a liquid flow caused by non-electrokinetic forces. (Claim 7), nor do they disclose a plastic part surface without coat being hydrophilized by a plasma treatment or oxidation agent in order to introduce functional groups that allow for a subsequent attachment of a coat onto the part surface. (Claim 27)

Relevant to claim 7, Regnier et al disclose microfluidic systems of conventional design (i.e. injection tee, Figures 8-10), with plural functional parts (i.e. branches) that define their volume. Regnier et al also disclose bulk fluid motion caused by non-electrokinetic means. (Column 37, lines 53-59)

Relevant to claim 7, Zimmer et al disclose the ability of capillaries with sufficiently hydrophilic surfaces, including polymer surfaces, to draw in aqueous materials upon contact. (Pages 5-8)

Relevant to claim 27, Van Alstine discloses the preparation of a plastic substrate for coating by plasma treatment, in order to introduce reactive surface groups. (Column 6, lines 14-21 and 31-39)

Regarding claim 7, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Karger by specifically using the conventional injection tee used for electrophoresis in microfluidic devices, as taught by Regnier et al, because it provides simple control of the injected sample volume, as taught by Regnier at Column 35, lines 28-33. Such injection tees were the basic conventional geometry used in the field of microfluidic systems at the time of the invention, and use of this geometry in the suggested microfluidic system of Karger et al (Column 2, lines 27-32) would have been obvious to a skilled artisan.

It would also have been obvious to one having ordinary skill in the art to further modify the device of Karger et al by using a non-electrokinetic means of moving fluid within the channels, as also taught by Regnier et al, because it would prevent electrophoretic bias in the injection procedure.

Regarding claim 7, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device of Karger et al by providing a surface of sufficient hydrophilicity at a channel opening to draw aqueous fluids in by capillarity, as taught by Zimmer et al, because it would facilitate sample introduction in some applications. (e.g. biosensor) Capillary action is a conventional technique for sample introduction in techniques using tubular capillaries, and its

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extension to microfluidic chips involves no inventive skill. Indeed, entry of liquid by “self-suction” would inherently result from bringing a drop of aqueous liquid in contact with any inlet of a dry microfluidic system coated with a hydrophilic polymer, such as that disclosed by Karger.

Regarding claim 27, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Karger et al by preparing the plastic substrate for coating by plasma treatment, as taught by Van Alstine et al, because it would provide a dry, less labor-intensive means of surface preparation.

Also regarding the question of optimization, generally, differences in concentration (i.e. in this case, density, thickness, or other variable of the coating) or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

13. Applicant's arguments filed on 21 March 2006 have been fully considered but they are not persuasive.

Applicant argues that Amigo strongly and exclusively teaches only electrokinetic transport in his system, that any alteration of this would not be obvious based on the

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teachings of Amigo, and would change the key teaching of the reference. The Examiner respectfully disagrees. It is true that Amigo primarily teaches electrophoresis, but he also teaches modification of electroosmosis, including its minimization or elimination in the channels. If electroosmosis is eliminated, obviously a non-electrokinetic means of fluid transport will be necessary in the system. Amigo even uses such means in preparing the coating within his system. (Column 9, lines 45-48) By itself, this argues strongly that Amigo's device in itself meets the very broad new limitation to a device merely "adapted for" mass transport as claimed, but the reliance on Regnier et al is maintained to show that non-electrokinetic means were known in the art and used in devices of this type. At the time of Amigo's work, pressure-based fluid manipulation in microfluidic systems was quite conventional and well known, and the Examiner maintains that addition of conventional means for their intended purpose would have been obvious to one having ordinary skill in the art. The Examiner also points out that motivation for modification need not lie in the primary reference, but may also be given by teaching references or the knowledge of one having ordinary skill in the art.

Furthermore, Applicant's disclosure gives absolutely no indication that a non-electrokinetic means of fluid movement is a significant part of the claimed invention. The disclosure at Page 13, lines 4-22 describes suitable means of causing fluid flow, and lists electrokinetic means (e.g. electroendoosmosis and electrophoresis) and non-electrokinetic means, with no indication that either is preferable.

In the arguments against the rejection of Claims 7 and 27, applicant argues that Karger et al teaches electrophoresis or HPLC as the only means of fluid transport. If this is true, HPLC conventionally utilizes a non-electrokinetic means of fluid transport, which meets the new limitation of Claim 7. Applicant's other arguments regarding these rejections are moot in view of the new grounds of rejection that were necessitated by the amendment.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 9:00 am – 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
31 May 2006


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PRIMARY EXAMINER
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